Paper No. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte WILLIAM M. KLEINFELTER

Appeal No. 2005-0493
Application No. 09/348,774

HEARD: May 4, 2005

Before KRASS, BARRY, and SAADAT, *Administrative Patent Judges.*
BARRY, *Administrative Patent Judge.*

DECISION ON APPEAL

A patent examiner rejected claims 1-49. The appellant appeals therefrom under 35 U.S.C. § 134(a). We reverse.

BACKGROUND

The invention at issue on appeal concerns prescription drugs. According to the appellant, pharmaceutical companies spend billions of dollars to promote new prescription drugs to physicians and dentists (collectively "health care specialists"). For example, salesmen meet health care specialists to present the benefits of new prescription drugs. (Spec. at 1.) Unlike in standard retail sales, however, no purchase

takes place at such meetings. (*Id)* The success of a salesman is determined based on the writing of a new prescription. (*Id* at 1-2.) More specifically, a pharmacist fills a prescription by entering data on a prescribed drug into a computer. Pharmaceutical companies treat such an entry as a newly prescribed drug. (*Id.* at 2.)

The prescription, however, may have been for renewal or refill of an existing medication. Furthermore, if a patient changes pharmacies, the appellant explains, no data are conveyed to the pharmaceutical companies about the patient's previous prescriptions at another pharmacy. (*Id.*)

In contrast, the appellant's invention determines whether a drug has been previously prescribed by comparing a current prescription for the drug with prior prescriptions for drugs. Their invention also determines whether a drug is a replacement for a drug previously given to a patient by comparing illnesses treatable by a currently prescribed drug with illnesses treatable by previously prescribed drugs.

A further understanding of the invention can be achieved by reading the following claims.

1. A computer implemented method for processing prescription data representing a plurality of prescription drugs, said method comprising the steps of:

arranging received prescription data that corresponds to a first prescription drug into a new record of a predetermined format containing an identifier for identifying said patient and further containing a first name of said first prescription drug;

accessing a plurality of pre-stored records of said predetermined format, each pre-stored record containing information on a plurality of prescription drugs previously prescribed for respective patients;

comparing said identifier in said new record with each identifier located in the pre-stored records to find a matching pre-stored record associated with said patient;

comparing said first name of said first prescription drug with a second name of a second prescription drug located in the found matching pre-stored record; and

identifying said first prescription drug as a new therapy start for said patient if said first name is not substantially identical to said second name.

26. A computer implemented method for processing prescription data using a plurality of pre-stored prescription data records, each of which comprises a patient identifier identifying a patient and a drug identifier identifying a drug being prescribed to the identified patient of the respective record, the method comprising:

receiving a first prescription data record comprising a patient identifier identifying a first patient and a drug identifier identifying a drug being prescribed to the first patient;

comparing the patient identifier of the first prescription data record to the patient identifier of each of the plurality of pre-stored prescription data records to find all pre stored prescription data records having a patient identifier matching the patient identifier of the first prescription data record;

identifying all the illnesses treatable by the drug being prescribed of the first prescription data record;

for each matching pre-stored prescription data record, identifying all the illnesses treatable by the drug being prescribed of the respective pre-stored prescription data record; and

determining whether the drug being prescribed of the first prescription data record is a therapy switch based on the illnesses treatable by the drug being prescribed of the first prescription and the illnesses treatable by any drug being prescribed of any of the matching pre stored prescription data records.

Claims 1-49 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,950,630 ("Portwood").

OPINION

Rather than reiterate the positions of the examiner or the appellant *in toto*, we focus on the points of contention therebetween. The examiner asserts that Portwood's "tests conducted on drug—drug interaction and prior adverse reactions of a particular

patient to a prescribed drug include a determination using the GPI[1] and NDC[2] to determine whether the drug being prescribed is a new recommended prescription (new therapy start) or a continuing prescription." (Examiner's Answer at 23-24.)

The appellant argues, "each of these tests . . . compares a currently prescribed drug to information which cannot reveal whether the currently prescribed drug is a new therapy start," (Reply Br. at 4), and "the type of information against which the tests . . . compare a current prescription cannot reveal a therapy switch." (*Id.* at 6.)

In addressing the point of contention, the Board conducts a two-step analysis. First, we construe claims at issue to determine their scope. Second, we determine whether the construed claims would have been obvious.

1. CLAIM CONSTRUCTION

"Analysis begins with a key legal question — *what* is the invention *claimed*?" *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1567, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987). In answering the question, "[c]laims are not interpreted in a vacuum, but are part of and are read in light of the specification." *Slimfold Mfg. Co. v. Kinkead Indus.,*

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[1] The "Generic Product Identifier (GPI) . . . is a listing of available drugs coded by their generic chemical composition. . . ." Portwood, col. 1, ll. 51-53.

[2] The "National Drug Code (NDC) . . . is a listing of available drugs coded by their trade names." *Id.* at ll. 53-54.

Inc., 810 F.2d 1113, 1116, 1 USPQ2d 1563, 1566 (Fed. Cir. 1987) (citing *Hybritech Inc. v. Monoclonal Anti-bodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94-95 (Fed. Cir. 1986); *In re Mattison*, 509 F.2d 563, 565, 184 USPQ 484, 486 (CCPA 1975)).

Here, independent claim 1 recites in pertinent part the following limitations:

> accessing a plurality of pre-stored records of said predetermined format, each pre-stored record containing information on a plurality of prescription drugs previously prescribed for respective patients;
>
> comparing said identifier in said new record with each identifier located in the pre-stored records to find a matching pre-stored record associated with said patient;
>
> comparing said first name of said first prescription drug with a second name of a second prescription drug located in the found matching pre-stored record; and
>
> identifying said first prescription drug as a **new therapy start** for said patient if said first name is not substantially identical to said second name.

(Emphasis added.) Independent claims 10, 19, and 20 recite similar limitations. For its part, the appellant's specification describes a "new therapy" and a "therapy start" as "a newly prescribed drug. . . ." (Spec. at 2.) Reading the limitations in light of the specification, claims 1,10, 19, and 20 determine whether a drug has been previously prescribed by comparing a current prescription for the drug with prior prescriptions for drugs.

Independent claim 26 recites in pertinent part the following limitations:

> comparing the patient identifier of the first prescription data record to the patient identifier of each of the plurality of pre-stored prescription data records to find all pre stored prescription data records having a patient identifier matching the patient identifier of the first prescription data record;
>
> identifying all the illnesses treatable by the drug being prescribed of the first prescription data record;
>
> for each matching pre-stored prescription data record, identifying all the illnesses treatable by the drug being prescribed of the respective pre-stored prescription data record; and
>
> determining whether the drug being prescribed of the first prescription data record is a **therapy switch** based on the illnesses treatable by the drug being prescribed of the first prescription and the illnesses treatable by any drug being prescribed of any of the matching prestored prescription data records.

(Emphasis added.) Independent claims 29, 35, 39, and 45 recite similar limitations. For its part, the appellants' specification describes a "therapy switch" as "a replacement . . . for the drug previously given to the patient." (Spec. at 11.) Reading the limitations in light of the specification, claims 26, 29, 35, 39, and 45 determine whether a first drug is a replacement for a drug previously given to a patient by comparing illnesses treatable by the first drug with illnesses treatable by previously given drugs.

2. OBVIOUSNESS DETERMINATION

Having determined what subject matter is being claimed, the next inquiry is whether the subject matter would have been obvious. "In rejecting claims under 35 U.S.C. Section 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness." *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)). "'A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.'" *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 USPQ 143, 147 (CCPA 1976)).

Here, Portwood "provide[s] a system that identifies for [a] treating physician possible dosing, administering duration, or drug interaction problems that might result from a prescribed medication regimen." Col. 2, ll. 19-22. The system employs several procedures to identify such problems, two of which the examiner cites, *supra*. A "Drug Interaction Checking Procedure," col. 15, l. 6, "determine[s] if any of the drugs included within the medical regimen will cause an unacceptable reaction with any other drug included within the medical regimen." *Id.* at ll. 10-13. To do so, a "prescriber [central processing unit ("CPU")] 7 is programmed to compare the classes of each drug in the

medical regimen to determine . . . if there would be any anticipated unacceptable drug interactions because of the compound classes in which a drug may be included." *Id.* at ll. 35-39. "If there are unacceptable reactions between drugs included within the medical regimen, the prescriber CPU 7 is programmed to display this information on the prescriber monitor 10. The prescriber then modifies one or more of the drugs to eliminate the unacceptable reaction." *Id.* at ll. 52-55. Although the Drug Interaction Checking Procedure analyzes the drugs in a medical regimen, we are unpersuaded that it teaches or would have suggested determining whether a drug in the regimen has been previously prescribed or whether the drug is a replacement for one previously given to a patient.

"Once . . . there are no unacceptable drug interactions," *id.* at ll. 61-62, a "Prior Drug Reaction Checking Procedure," *Id.* at l. 61, "search[es] the patient data to determine if the patient has ever reported any adverse reaction to any of the drugs, or classes of drugs, in the prescribed medical regimen." *Id.* at ll. 65-67. "If so, the prescriber CPU 7 is programmed to display this information on the prescriber monitor 10. The prescriber then modifies the prescribed medical regimen to eliminate the unacceptable known reaction." Col. 16, ll. 1-4. Although the Prior Drug Reaction Checking Procedure analyzes the drugs in a medical regimen, we are unpersuaded that it teaches or would have suggested determining whether a drug in the regimen has

been previously prescribed or whether the drug is a replacement for one previously given to a patient. Therefore, we reverse the obviousness rejection of claim 1; of claims 2-8, which depend from claim 1; of claim 10; of claims 11-17, which depend from claim 10; of claim 19; of claim 20; of claims 21-25, which depend from claim 20; of claim 26; of claims 27, 28, and 49, which depend from claim 26; of claim 29; of claims 30-34, which depend from claim 29; of claim 35; of claims 26-38, which depend from claim 35; of claim 39; of claims 40-44, which depend from claim 39; of claim 25; and of claims 46-48, which depend from claim 45.

CONCLUSION

In summary, the rejection of claims 1-49 under § 103(a) is reversed.

REVERSED

ERROL A. KRASS
Administrative Patent Judge

LANCE LEONARD BARRY
Administrative Patent Judge

MAHSHID D. SAADAT
Administrative Patent Judge

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